K080469

# 510(k) SUMMARY

## VIDAS® CA 15-3 Assay

**A. Submitter Information**

| | |
|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Sandra Perreand |
| Phone Number: | 314-731-8594 |
| Fax Number: | 314-731-8689 |
| Date of Preparation: | April 17, 2009 |

JUN 2 2 2009

**B. Device Name**

| | |
|---|---|
| Trade Name: | VIDAS® CA 15-3 Assay |
| Common Name: | CA 15-3 |
| Classification Name: | System, Test, CA 15-3, for monitoring and management of breast cancer |

**C. Predicate Device Name**

| | |
|---|---|
| Trade Name: | TOSOH Medical, Inc. ST AIA Pack BRCA |

**D. Device Description**

VIDAS CA 15-3 is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of CA 15-3 levels in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 15-3 assay is indicated for the serial measurement of CA 15-3 as an aid in the monitoring of disease progression or response to therapy in patients previously diagnosed with breast cancer.

CA 15-3 is a registered trademark from Fujirebio Diagnostics Inc. (formerly named Centocor Diagnostics of Pennsylvania, Inc.)

The assay principle combines a two-step immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), a pipette tip-like device, serves as the solid phase as well as the pipetting device for the assay. It is coated with mouse monoclonal 115D8 antibodies. The other assay reagents are ready-to-use and pre-dispensed in the sealed reagent strips (STRs). The individual kit components are described in detail on the following pages.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. This operation enables the monoclonal 115D8 antibody fixed onto the interior wall of the SPR to capture the reactive antigenic determinants present in the sample. Unbound components are eliminated during the washing steps. Alkaline phosphatase labeled monoclonal DF3 antibody

(conjugate) is then incubated in the SPR where it binds with the CA 15-3 reactive antigenic determinant. Unbound conjugate is then eliminated during the washing steps.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of CA 15-3 reactive antigenic determinants present in the sample.

At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

## E. Intended Use

VIDAS® CA 15-3 is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of CA 15-3 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 15-3 is indicated for the serial measurement of CA 15-3 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with breast cancer for disease progression or response to therapy in conjunction with other clinical methods. The VIDAS CA 15-3 assay can also be used as an aid in the detection of recurrence in previously treated Stage II and III breast cancer patients.

## F. Technological Characteristics Summary

A general comparison of the similarities and differences of the VIDAS CA 15-3 assay to the predicate device is presented in the table below.

| Item | VIDAS® CA 15-3 Assay | TOSOH ST AIA-PACK BRCA (k010796) |
|---|---|---|
| **General Comparison** | | |
| **Intended Use** | VIDAS® CA 15-3 is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of CA 15-3 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 15-3 is indicated for the serial measurement of CA 15-3 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with breast cancer for disease progression or response to therapy in conjunction with other clinical methods. The VIDAS CA 15-3 assay can also be used as an aid in the detection of recurrence in previously treated Stage II and III breast cancer patients. | ST AIA-PACK BRCA is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of CA27.29 in human serum on TOSOH AIA Nex·IA and AIA-600 II Immunoassay analyzers. ST AIA-PACK BRCA is to be used as an aid in monitoring response to therapy for patients with Stage IV (metastatic) breast cancer as well as determining early recurrence in Stage II and Stage III breast cancer patients who were previously treated and free of disease. Serial testing for patient CA27.29 assay values should be used in conjunction with other clinical methods used for monitoring response to therapy in patients with Stage IV metastatic breast cancer and for detecting early recurrence in Stage II and Stage III disease. |
| **Specimen** | Serum | Serum |
| **Analyte** | CA 15-3 | CA 27.29 (CA15-3) |

| Item | VIDAS® CA 15-3 Assay | TOSOH ST AIA-PACK BRCA (k010796) |
|---|---|---|
| **General Comparison** | | |
| **Antibody** | mouse monoclonal 115D8 and DF3 antibodies | mouse monoclonal antibodies to CA 15-3 |
| **Assay Principle** | Two antibody "sandwich" binding of CA 15-3 antigen. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound | Two antibody "sandwich" binding of CA 27.29. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound |
| **Automated** | Yes | Yes |
| **Assay Technique** | Enzyme-linked fluorescent assay (ELFA) | Two-site immunoenzymometric assay |
| **Sample Volume** | 100 µL | 20 µL |
| **Traceability/ Standardization** | Master curve for each kit lot and each calibrator lot are traceable to working standards established by bioMérieux, Inc. and value assigned by the Fujirebio Diagnostics, Inc. radioimmunoassay method | Each calibrator lot are traceable to internal reference standards |
| **Measurement range** | 2.00 – 365 U/mL | 2.0 – 400 U/mL |

## G. Performance Data

A summary of the non-clinical and clinical test results is presented in the table below.

| Test | VIDAS® CA 15-3 Assay | TOSOH ST AIA-PACK BRCA (K010796) |
|---|---|---|
| **Non-clinical (Analytical) Comparison** | | |
| **Intra-Assay Precision** | n = 40 replicates, 2 lots, 3 sites<br>Pool A: Mean = 270.0 U/mL<br>CV = 2.1 – 4.0%<br><br>Pool B: Mean = 67.7 U/mL<br>CV = 3.2 – 4.5%<br><br>Pool C: Mean = 21.4 U/mL<br>CV = 2.3 – 4.1% | n = 10 replicates<br>Control L: Mean = 41.3 U/mL<br>CV = 2.2%<br><br>Control H: Mean = 300.9 U/mL<br>CV = 1.4% |
| **Inter-Run Precision** | n = 20 runs<br>Pool A: Mean = 270.0 U/mL<br>CV = 0.0 – 1.2%<br><br>Pool B: Mean = 67.7 U/mL<br>CV = 0.0 – 1.4%<br><br>Pool C: Mean = 21.4 U/mL<br>CV = 0.6 – 2.2% | n = 21 runs<br>Control L: Mean = 40.4 U/mL<br>CV = 2.2%<br><br>Control H: Mean = 301.0 U/mL<br>CV = 2.2% |
| **Limits of Detection** | 0.724 U/mL (< 2.0 U/mL) | 2.0 U/mL |

| Clinical Comparison | | |
|---|---|---|
| **Item** | **VIDAS® CA 15-3 Assay** | **TOSOH ST AIA-PACK BRCA (k010796)** |
| **Reference Range** | Females, ≤ 50 years (95% percentile) = 22.07 – 24.09 U/mL<br>Females, > 50 years (95% percentile) = 29.62 – 36.95 U/mL<br>All females (95% percentile) = 26.99 – 32.07 U/mL | Females, pre-menopausal (99% order statistic) = 28.6 – 44.3 U/mL<br>Females, post-menopausal (99% order statistic) = 38.9 – 43.4 U/mL<br>All females (99% order statistic) = 34.8 – 44.3 U/mL<br>Male (99% order statistic) = 36.0 – 84.8 U/mL |
| **Method Comparison** | | |
| Methods | X = TOSOH ST AIA-Pack BRCA; y = VIDAS® CA 15-3 | |
| Number of patients | 1,035 samples | |
| Results | Slope = 0.96 (95% confidence interval = 0.83 to 1.09)<br>Intercept = -1.94 (95% confidence interval = -4.90 to +1.01) | |

## H. Conclusion

**The VIDAS® CA 15-3 Assay is substantially equivalent to the Tosoh Medical, Inc. TOSOH ST AIA-PACK BRCA**

The 510(k) summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 22 2009

BioMérieux, Inc.
c/o Ms. Sandra L. Perreand
Senior Director, North American Regulatory Affairs
595 Anglum Rd
Hazelwood, MO 63042

Re: k080469
Trade/Device Name: VIDAS® CA 15-3
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LTK
Dated: February 26, 2009
Received: February 27, 2009

Dear Ms. Perreand,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding

of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k080469

Device Name: VIDAS® CA 15-3

Indication for Use:

VIDAS® CA 15-3 is an automated quantitative test for use on the VIDAS instruments for the quantitative measurement of CA 15-3 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 15-3 is indicated for the serial measurement of CA 15-3 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with breast cancer for disease progression or response to therapy in conjunction with other clinical methods. The VIDAS CA 15-3 assay can also be used as an aid in the detection of recurrence in previously treated Stage II and III breast cancer patients.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k080469